K091292

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 2 5 2009

1. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: BD Diagnostics, Preanalytical Systems
  1 Becton Drive, MC300
  Franklin Lakes, NJ 07417
- Registration Number: 1024879
- Contact Person: Mary Ann Alsberge
  Regulatory Affairs Specialist
  BD Diagnostics, Preanalytical Systems
  Telephone No.:(201) 847-3103
  Fax No. (201) 847-4858
- Date of Summary: May 1, 2009

Device

- Trade Name: BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube
- Classification Name: JKA (Tubes, vials, systems, serum separators, blood collection)
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

2. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

➢ Device Description:

BD Vacutainer® Tubes are sterile, single-use, evacuated plastic blood collection tubes with rubber stoppers that provide a means of collecting, transporting, separating, and processing blood in a closed tube. The BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube (BD RST) clots blood specimens much faster than other additives (5 minutes), and therefore is desirable when a fast turn-around-time is necessary.

➢ Intended Use:

The BD RST is a single use tube used to collect, separate, transport and process venous blood specimens to obtain serum for chemistry determinations for *in vitro* diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

The BD RST is not recommended for patients on heparin therapy, direct thrombin inhibitor therapy or with Factor I deficiency.

➢ Claims:

- BD RST tube clots blood in 5 minutes.
- BD RST tube demonstrates substantially equivalent performance to the predicate BD Vacutainer® SST™ Plus Blood Collection tube (BD SST™) for the collection, separation, transport, and processing of venous blood specimens for chemistry determinations requiring serum for *in vitro* diagnostic use.
- BD RST tube demonstrates substantially equivalent performance to the predicate BD SST™ tube for the following selected serology analytes: anti-CMV IgG, anti-CMV-IgM, and CRP.
- BD RST tube demonstrates substantially equivalent performance to the predicate BD SST™ tube for the following selected immunology analytes: C3, C4, IgG, IgM, and Rf.
- BD RST tube demonstrates substantially equivalent performance to the predicate BD SST™ tube for 24 hr stability for analytes evaluated except LDL (19 hours) and Triglycerides (6 hours).

➢ Synopsis of Test Methods and Results

Clinical testing was performed on blood collected in both the evaluation and predicate tubes for a battery of routine and special chemistry analytes, and selected serology and immunology analytes. Clotting of blood within 5 minutes was demonstrated in the BD RST. The test results demonstrated that the evaluation device's performance was substantially equivalent to the legally marketed predicate device for tested analytes.

Based on a comparison of the device features, materials, and intended use, the BD RST is substantially equivalent to the commercially available predicate device, the BD SST™ tube.

Mary Ann Alsberge
Regulatory Affairs Specialist
BD Diagnostics, Preanalytical Systems

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Becton Dickinson & Company
c/o Ms. Mary Ann Alsberge
Regulatory Affairs Specialist
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417

AUG 2 5 2009

Re: k091292
Trade Name: BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube
Regulation Number: 21 CFR §862.1675
Regulation Name: Blood specimen collection devices.
Regulatory Class: Class II
Product Codes: JKA
Dated: July 21, 2009
Received: July 22, 2009

Dear Ms. Alsberge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k091292

Device Name: BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube

Indication For Use:

The BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube (BD RST) is a single use tube used to collect, separate, transport and process venous blood specimens to obtain serum for chemistry determinations for *in vitro* diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

The BD RST is not recommended for patients on heparin therapy, direct thrombin inhibitor therapy or with Factor I deficiency.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091292